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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/023,952 | 12/21/2001 | Kjell Ekberg | 48266-61462CIP | 5291 |

466 7590 11/30/2004

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ARLINGTON, VA 22202

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| EXAMINER |
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JASTRZAB, KRISANNE MARIE

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| ART UNIT | PAPER NUMBER |
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1744

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,952

Applicant(s)

EKBERG ET AL.

Examiner

Krisanne Jastrzab

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/623,834.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/21/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising". Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: the continuing information on the first page should be updated to reflect the current status of the parent application.

Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement filed 12/21/2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicant referred to having copies filed previously in the parent case, however, not all of the foreign references cited were found in the parent case, and as such, have not been considered.

Claim Objections

Claim 6 is objected to because of the following informalities: "a plurality of segment" should be —segments—in line 2, thereof. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, the use of "preferably" is found to be vague and indefinite because it is unclear as to whether or not this phrase is intended to limit the scope of the invention.

With respect to claims 10-11, these claims are found to be vague and indefinite because they each depend from claim 1, but refer to the determination of whether or not the concentration is constant, however, the requirement for constant concentration is not introduced until claim 8. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Siepmann et al., U.S. patent No. 5,324,666, Conrad U.S. patent No. 6,235,207 or Wainwright U.S. patent No. 5,052,382, in view of both Masuda U.S. patent No. 5,120,512 and Karlson U.S. patent No. 5,069,880.

Siepmann et al., teaches the application of an ozone fluid for sterilization with continuous monitoring of the ozone concentration in two phases, immediately prior to application and immediately following application, with a comparison of the two measurements to ensure that equalized and complete ozone treatment is achieved. Siepmann et al., is directed to the treatment of sewage and is silent as to the application to an object. See column 2, lines 47-56, column 3, and column 6, lines 49-61.

Conrad teaches a method of measuring the degree of treatment of a medium by a gas such as ozone, by monitoring to determine that a predetermined condition has been met, namely that a given concentration has been maintained. Conrad teaches a comparison methodology to ensure that treatment has been achieved by a differential in

a pre-treatment vs. post-treatment state. See column 3, lines 25-50, column 6, lines 21-23, and column 7, lines 5-60 and column 12, lines 1-11.

Wainwright teaches control of generation and administration of ozone utilizing two monitoring means, one for concentration of the amount of ozone generated and one for the concentration of ozone after use to ensure that the required concentration has been delivered in the predetermined required time frame. See column 1, lines 42-58, column 5, lines 29-45, column 7, lines 4-21 and lines 40-45 and column 8, lines 10-65.

Masuda teaches the sterilization of objects, such as dental handpieces, having confined internal lumens, with ozone gas by delivery of the gas through a closed sterilization chamber containing the objects. Masuda teaches desired concentrations of ozone for achieving sterilization of the objects. See column 3, lines 10-68.

Karlson teaches the sterilization of objects such as medical instrument with the application of ozone gas or ozonated water. The ozone fluid is flowed into contact with all surfaces of the instrument including tubes and small spaces therein. Karlso teaches the monitoring of the concentration of ozone exiting the object treatment zone for controlling the sterilization process, but not in a comparison format to a measurement taken of the initial, pre-treatment ozone. See column 7, lines 40-68 and column 8.

It would have been obvious to one of ordinary skill in the art to apply the method of ozone application and concentration monitoring control of any one of Siepmann et al., Conrad or Wainwright, in ozone processes including objects as taught in both Karlson and Masuda, because such control would ensure precision in optimizing concentration

parameters for sterilization of the objects being treated, particularly with the given recognition of the importance of concentration levels in all of the above references.

With respect to claim 6, both Karlson and Masuda clearly teach the application of ozone to medical instruments having internal tubes and small spaces and it would have been obvious to apply that same method to any construction of apparatus having a structure that restricts flow, including segmented channels.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

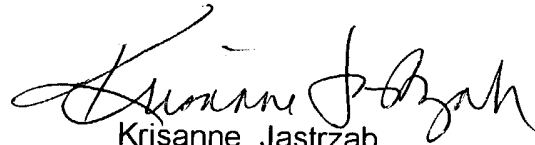
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Krisanne Jastrzab". The signature is fluid and cursive, with the first name "Krisanne" and last name "Jastrzab" clearly distinguishable.

Krisanne Jastrzab
Primary Examiner
Art Unit 1744

November 29, 2004